Regimen Monograph

A - Regimen Name

BEP(3D) Regimen

Bleomycin-Etoposide-PLATINOL ® (CISplatin)

Disease Site	Genitourinary - Testis
Intent	Adjuvant Curative (Adjuvant - In clinical stage 1 non-seminomatous testicular cancer, may be used as adjuvant treatment for patients who are unsuitable for primary surveillance, or who prefer immediate treatment.)
Regimen Category	**Evidence-Informed :** Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.
Rationale and Uses	Treatment of patients with non-seminomatous testicular cancer

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B - Drug Regimen

bleomycin	15 units /m²	IV (max. 30 units per dose) or 30 units fixed dose *Days 1, 8 & 15

(*Days may be adjusted to fit clinic schedule)

etoposide (Round to nearest 10mg)	165 mg /m²	IV	Days 1 to 3
CISplatin (Round to nearest 1mg)	50 mg /m²	IV	Days 1 to 2

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For a usual total of 3 to 4 cycles (Adjuvant setting: Up to 2 cycles)

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D - Premedication and Supportive Measures

Antiemetic Regimen: High (D1-3)
Minimal (D8, 15)

Febrile Neutropenia Risk: High

Other Supportive Care:

- Premedication may be given to prevent hypersensitivity reactions. (e.g. - hydrocortisone IV and/or diphenhydramine, and optional acetaminophen)

• Standard regimens for Cisplatin premedication and hydration should be followed. Refer to local guidelines

- Fertility counselling and sperm bank should be routinely offered.

Also refer to CCO Antiemetic Recommendations.

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated. As dose modification of BEP treatment may compromise its efficacy, it is recommended that modification of this regimen be done only after discussion with a medical oncologist experienced in the treatment of testicular cancer. Therefore, specific recommendations are not provided.

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F - Adverse Effects

Refer to bleomycin, etoposide, CISplatin drug monograph(s) for additional details of adverse effects

Most frequently occurring adverse effects:

- Nausea and vomiting
- Nephrotoxicity
- Neurotoxicity (ototoxicity)
- Myelosuppression
- Stomatitis and diarrhea
- Skin changes and increased pigmentation
- Fevers (hypersensitivity)
- Pulmonary toxicity with Bleomycin at doses > 500 U
- Alopecia
- Infertility
- Fatigue

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G - Interactions

Refer to bleomycin, etoposide, CISplatin drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to bleomycin, etoposide, CISplatin drug monograph(s) for additional details

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I - Recommended Clinical Monitoring

Recommended Clinical Monitoring

- Clinical toxicity assessment (including local toxicity, neurotoxicity, ototoxicity, pulmonary).
- CBC before each cycle. Interim counts should be done in first cycle and repeated if dose modifications necessary.
- Chest x-ray before each cycle.
- Baseline and regular liver and renal function tests (including electrolytes and magnesium), and urinalysis.
- Routine pulmonary function test, if more than 9 weeks of Bleomycin treatment is planned.
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

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J - Administrative Information

Approximate Patient Visit	Days 1-3: 2-3 hours; Bleomycin only: 0.5 hours
Pharmacy Workload (average time per visit)	23.727 minutes
Nursing Workload (average time per visit)	46.467 minutes

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K - References

de Wit R, Roberts T, Wilkinson PM et al. Equivalence of three or four cycles of bleomycin, etoposide, and cisplatin chemotherapy and of a 3- or 5- day schedule in good-prognosis germ cell cancer: a randomized study of the European Organization for research and treatment of cancer genitourinary tract cancer cooperative group and the Medical Research Council. J of Clinical Oncology 2001, March 15; 19(6); 1629-40.

Williams S, Birch R, Einhorn LH et al. Treatment of disseminated germ-cell tumors with cisplatin, bleomycin, and either vinblastine or etoposide. N Engl J Med, 1987; 316: 1435-144.

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Regimen Monographs

Refer to the New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public funding information.

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Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

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